

A Guide to Locating Information on Vaccine Safety

National Immunization Program

March 2002

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Introduction

This guide was produced by the National Immunization Program, part of the Centers for Disease Control and Prevention, to help individuals research issues surrounding vaccine safety. It contains information about government and international agencies and programs, as well as other organizations and selected resources.

This document is divided into four sections:

- I. State, Local, and Federal Agencies and Programs
- II. International Organizations
- III. Other Vaccine-Safety Related Organizations/Resources
- IV. Selected Vaccine Safety-Related Publications and Products
 - A. Government Publications
 - B. Institute of Medicine (IOM) Reports and Publications
 - C. Books and Videos

I. State, Local, and Federal Agencies and Programs

For general information on immunization, vaccine safety, clinics administering vaccines and school-entry requirements, contact your state or local health department.

State health departments on-line: www.cdc.gov/nip. Click on “partners.”

Immunization grantees (National Immunization Program) and program managers -- see Appendix H, “Immunization Resources.”

National Immunization Program (NIP)
Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, NE, MS E-05

Atlanta, GA 30333

Web site: www.cdc.gov/nip

National Immunization Information Hotline (Monday-Friday, 8:00am-11:00pm EST):

English: (800) 232-2522

Spanish: (800) 232-0233

E-mail: nipinfo@cdc.gov

The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) provides leadership for the planning, coordination, and implementation of immunization activities nationwide. The program helps monitor the safety and efficacy of vaccines by linking vaccine administration information with adverse event reporting and disease outbreak patterns. Through its toll-free telephone numbers and web site, NIP answers frequently asked questions about vaccines and vaccine safety, provides immunization schedules, and distributes vaccine-related publications.

Vaccine Adverse Event Reporting System (VAERS)

P.O. Box 1100

Rockville, MD 20849-1100

Information Line: (800) 822-7967 (24 hours)

Web site: www.vaers.org

VAERS is a national reporting system jointly administered the CDC and FDA to receive and analyze reports about adverse events that may be associated with vaccines. VAERS encourages the reporting of all clinically significant adverse events following any vaccine, whether or not the vaccine is believed to be the cause of the event. Health care providers, vaccine manufacturers, and consumers can report an adverse event 24 hours a day.

Clinical Immunization Safety Assessment (CISA) Network

National Immunization Program, CDC

Vaccine Safety and Development Branch

Epidemiology and Surveillance Division

1600 Clifton Road, NE

MS E-61

Atlanta, GA 30333

(404) 639-8256

Web site: CISA will have a link on the NIP web site in the near future, www.cdc.gov/nip

The Clinical Immunization Safety Assessment (CISA) Network was initiated in October 2001.

Patients who have experienced adverse events following vaccination will be referred to a coordinated network of CISA academic centers to undergo enhanced clinical evaluation. The results of these evaluations will be used to gain a better understanding of the mechanisms underlying these events and to help develop protocols and guidelines for health care providers to help them manage similar situations. CISA centers will also serve as regional information sources to address clinical vaccine safety questions.

**Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)**

1401 Rockville Pike

HSM-40

Rockville, MD 20852

(800) 835-4709 (voice information system)

FAX: (888) CBER-FAX (fax information system)

Web site: www.fda.gov/cber

E-mail: octma@cber.fda.gov

The Center for Biologics and Evaluation Research (CBER) of the Food and Drug Administration (FDA) regulates biological products such as vaccines, blood products, tissue, and related drugs and devices. It maintains a consumer information hotline to answer questions on vaccine safety and regulations and distributes materials such as guidelines and informational letters to manufacturers. CBER's web site contains current vaccine information, including recalls and withdrawals of vaccine products.

**Freedom of Information Staff (FOI)
Food and Drug Administration (FDA)**

5600 Fishers Lane

HFI-35

Rockville, MD 20857

(301) 827-6567

FAX: (301) 443-1726

Web site: www.fda.gov/foi

Congress passed the National Childhood Vaccine Injury Act of 1986 to help ensure vaccine safety and availability, and to compensate people injured by vaccines. The legislation covers specific vaccines administered routinely during childhood, and ensures that consumers are entitled to information describing specific adverse events that may occur following receipt of these vaccines. Consumers can obtain this information from reports filed with the Vaccine Adverse Events Reporting System (VAERS). However, if more information on specific reports is desired, consumers can file a Freedom of Information Act (FOIA) request using the unique VAERS Report Identification Numbers.

**National Vaccine Injury Compensation Program (VICP)
Health Resources and Services Administration (HRSA)**

Parklawn Building, Room 8A-35

5600 Fishers Lane

Rockville, MD 20857

(800) 338-2382

FAX: (301) 443-8196

Web site: www.hrsa.gov/osp/vicp

The National Childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program (VICP) to compensate those who suffer certain vaccine-related injuries or death, while protecting doctors and manufacturers from lawsuits. Coordinated through the Health Resources and Services Administration (HRSA), the program office distributes an information package detailing criteria for eligibility, how to file a claim, and required documentation.

National Vaccine Program Office (NVPO)

4770 Buford Highway

MS K-77

Atlanta, GA 30341

(770) 488-2040

FAX: (770) 488-2064

Web site: www.cdc.gov/od/nvpo

E-mail: nvpo@cdc.gov

The National Vaccine Program Office (NVPO) was created in 1986 to coordinate and integrate immunization-related activities among all federal agencies, including the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, and the Health Resources and Services Administration. NVPO also develops and implements strategies designed to increase levels of immunization coverage and decrease levels of adverse reactions to vaccines.

II. International Organizations

Department of Vaccines and Biologicals

World Health Organization (WHO)

Avenue Appia 20

1211 Geneva 27

Switzerland

(+00 41 22) 791 21 11

FAX: (+00 41 22) 791 3111

Web site: www.who.int/vaccines

E-mail: vaccines@who.int

The World Health Organization was founded in 1948 by the United Nations to cooperate with national governments in the strengthening of health programs, technology, and information. The Department of Vaccines and Biologicals was established by WHO with the goal of protecting all people at risk against vaccine-preventable diseases. The program comprises five units: (1) Expanded Programme on Immunization, (2) Vaccine Development, (3) Quality Assurance and Safety of Biologicals, (4) Vaccine Assessment and Monitoring, and (5) Access to Technologies.

Division of Vaccines and Immunization (HVP)

Pan American Health Organization (PAHO)

525 23rd Street, NW

Washington, DC 20037

(202) 974-3000

FAX: (202) 974-3663

Web site: www.paho.org

E-mail: hvp@paho.org

Established in 1902, the Pan American Health Organization is the oldest continuously functioning international public health agency. The Division of Vaccines and Immunization (HVP) was established in 1999 and incorporates the former Special Program for Vaccines and Immunization. The division supports member states in the Region of the Americas by improving policies governing the adoption and delivery of vaccination programs, and by promoting the strengthening, development, and production of high-quality vaccines throughout the Region.

Global Alliance for Vaccines and Immunization (GAVI)

Lisa Jacobs

GAVI Secretariat

c/o UNICEF

Palais des Nations

1211 Geneva 10

Switzerland

41.22.909.50.19

FAX: 41.22.909.59.31

Web site: www.vaccinealliance.org

E-mail: Gavi@unicef.org

GAVI is a coalition of global leaders in immunization including UN organizations, national governments, foundations, NGO's, and the pharmaceutical industry, formed in response to stagnating global immunization rates and widening disparities in vaccine access among industrialized and developing countries.

III. Other Vaccine Safety-Related Organizations/Resources

American Academy of Pediatrics (AAP)

141 Northwest Point Boulevard

Elk Grove Village, IL 60007-1098

(847) 228-5005

FAX: (847) 228-5097

Web site: www.aap.org

E-mail: kidsdoc@aap.org

The American Academy of Pediatrics is an organization of 55,000 pediatricians dedicated to the health, safety and well-being of infants, children, adolescents, and young adults.

American Pharmaceutical Association (APhA)

2215 Constitution Avenue, NW

Washington, DC 20037-2985

(202) 628-4410

FAX: (202) 783-2351

Web site: www.aphanet.org

The American Pharmaceutical Association is an organization of over 50,000 pharmacists and allied health professionals involved in ongoing efforts to improve public health by educating its members and the public about the pharmaceutical profession and its products, including vaccines.

Immunization Action Coalition (IAC)

1573 Selby Avenue

Suite 234

Saint Paul, MN 55104

(651) 647-9009

FAX: (651) 647-9131

Web site: www.immunize.org

E-mail: admin@immunize.org

The Immunization Action Coalition (IAC) is a nonprofit organization that promotes physician, community, and family awareness of, and responsibility for, appropriate immunization of people of all ages against vaccine-preventable diseases. The Hepatitis B Coalition is a program of IAC that promotes hepatitis B vaccination for all infants, children, and adolescents; hepatitis B screening for all pregnant women; testing and vaccination for high-risk groups; and education and treatment for hepatitis B carriers. Semi-annual newsletters containing valuable resources and news are available for both programs.

The Immunization Gateway: Your Vaccine Fact-Finder

Web site: www.immunofacts.com

This site is an online vaccine/immunization fact-finder that links to many of the latest resources on vaccines. It is produced by Facts and Comparisons, a commercial publisher of drug-related information.

Infectious Diseases Society of America (IDSA)

66 Canal Center Plaza

Suite 600

Alexandria, VA 22314

877-341-6644

FAX: (703) 299-0204

Web site: www.idsociety.org

E-mail: info@idsociety.org

The Infectious Diseases Society of America seeks to provide comprehensive information on infectious disease prevention to health care providers and the general public. IDSA sponsors the Vaccine Initiative, which communicates the benefits of routine immunization.

Institute for Vaccine Safety

The Johns Hopkins University
Bloomberg School of Public Health
615 North Wolfe Street
Suite W5515
Baltimore, MD 21207
(410) 955-2955
FAX: (410) 502-6733

Web site: www.vaccinesafety.edu

E-mail: info@vaccinesafety.edu

Established in 1997, the purpose of the Institute for Vaccine Safety is to obtain and distribute objective information on vaccines and vaccine safety to physicians, the general public, decision makers, and the media. It also investigates vaccine safety questions when data are inconclusive and conducts vaccine safety evaluations following vaccine licensure.

National Network for Immunization Information (NNii)

Infectious Diseases Society of America
66 Canal Center Plaza
Suite 600
Alexandria, VA 22314
(877) 341-6644
FAX: (703) 299-0204

Web site: www.immunizationinfo.org

E-mail: nnii@idsociety.org

The National Network for Immunization Information (NNii) provides up-to-date, science-based information about immunization to the public, health professionals, policy makers, and the media to help them understand the issues involved and make informed decisions. NNii is a partnership of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society of America, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Nurses Association, and the National Association of Pediatric Nurse Practitioners.

National Partnership for Immunization (NPI)

Web site: www.partnersforimmunization.org

A joint program of the National Foundation for Infectious Diseases and the National Healthy Mothers, Healthy Babies Coalition, the National Partnership for Immunization (NPI) seeks to increase national awareness of the importance and acceptance of immunization across the life span through outreach partnerships with public and private organizations. NPI develops educational initiatives and issues reports designed to improve immunization knowledge. NPI recently published a Reference Guide on Vaccines and Vaccine Safety.

Parents of Kids with Infectious Diseases (PKIDS)

P.O. Box 5666

Vancouver, WA 98668

(877) 55-PKIDS

FAX: (360) 695-6941

Web site: www.pkids.org

E-mail: pkids@pkids.org

The goal of Parents of Kids with Infectious Diseases (PKIDS) is to educate the public about infectious diseases, their prevention and transmission, and current medical advances. PKIDS also provides emotional, informational, and financial support to families of affected children and works to reduce the societal stigma associated with those who have infectious diseases.

The Vaccine Education Center at The Children's Hospital of Philadelphia

215-590-9990

Web site: www.vaccine.chop.edu

The Vaccine Education Center at The Children's Hospital of Philadelphia provides current information to parents and health care professionals about how vaccines work and are manufactured, whether vaccines are still necessary, their recommendation process, whether vaccines are safe, and their recommended schedules. The center also provides informational and audiovisual materials and speakers programs.

IV. Selected Vaccine Safety-Related Publications and Products**A. Government Publications****Advisory Committee on Immunization Practices (ACIP) Recommendations**

Advisory Committee on Immunization Practices (ACIP)

Division of Epidemiology and Surveillance

National Immunization Program

1600 Clifton Road, NE

MS E-61

Atlanta, GA 30333

(404) 639-8096

FAX: (404) 639-8520

Web site: www.cdc.gov/nip/acip. Click on "recommendations."

E-mail: acip@cdc.gov

The Advisory Committee on Immunization Practices (ACIP) is a committee composed of 15 experts in fields associated with immunization who provide recommendations designed to reduce the incidence of vaccine-preventable diseases and increase the safe usage of vaccines.

ACIP recommendations printed in Morbidity and Mortality Weekly Report (MMWR) can be accessed on-line through the National Immunization Program web site's sub-site for ACIP. In addition, the ACIP sub-site page for "recommendations" has a link to other recent articles about immunization that have been printed in MMWR.

Guide to Contraindications to Childhood Vaccinations

This booklet contains information on contraindication to recommended childhood vaccines. It was developed using information derived from the Standards for Pediatric Immunization Practices, recommendations of the Advisory Committee on Immunization Practices (ACIP), and those of the Committee on Infectious Diseases (Red Book Committee) of the American Academy of Pediatrics (AAP). This publication can be obtained on the NIP web site at www.cdc.gov/nip.

Parents Guide to Childhood Immunization (2001)

This newly revised 94-page booklet, available in English and Spanish, introduces parents to 12 childhood diseases and the vaccines that can prevent them, vaccine safety issues, a glossary of immunization terms, and the current childhood vaccination schedule. This publication can be obtained from the NIP web site at www.cdc.gov/nip.

Six Common Misconceptions About Vaccination and How to Respond to Them (1996)

This booklet discusses six misconceptions about vaccination often cited by parents as reasons they question the need to have their children immunized. Each misconception is refuted based on scientific information and research findings. The misconceptions include the concepts of community immunity, whether there are vaccine “hot lots,” vaccine side effects, and whether diseases still exist. This publication can be viewed on the NIP web site at www.cdc.gov/nip.

Vaccine Information Statements

The National Childhood Vaccine Injury Act requires that vaccine information materials be developed for each vaccine covered by the Act. These materials, known as *Vaccine Information Statements*, must be provided by all public and private vaccination providers each time a vaccine is administered. Copies of Vaccine Information Statements are available from state health authorities responsible for immunization, or they can be obtained from CDC's National Immunization Program website at <http://www.cdc.gov/nip>. Translations of Vaccine Information Statements into languages other than English are available from certain state immunization programs and from the Immunization Action Coalition website at <http://www.immunize.org>.

Task Force on Safer Childhood Vaccines: Final Report and Recommendations (1998)

National Institute on Allergy and Infectious Diseases (NIAID), NIH

Office of Communications and Public Liaison

Building 31, Room 7A-50

31 Center Drive

MSC 2520

Bethesda, MD 20892-2520

Web site: www.niaid.nih.gov/

A summary of the findings and recommendations of the Task Force on Safer Childhood Vaccines concerning improvements in research, manufacturing, licensing, distribution, administration, testing, and vaccine safety monitoring of childhood vaccines.

Vaccine Safety: What Parents Need to Know (pamphlet)

Michigan Department of Community Health
Information & Education Coordinator
Division of Immunization
4641 Willoughby Road
Holt, MI 48842
1-888-76-SHOTS
Web site: www.hpclearinghouse.org

What If You Don't Immunize Your Child (pamphlet)

California Department of Health Services
Immunization Branch
2151 Berkeley Way
Room 712
Berkeley, CA 94704
(510) 540-2381
FAX: (510) 540-2650
Web site: www.dhs.ca.gov

Plain Talk About Childhood Immunizations (booklet)

This booklet is produced by both the State of Alaska and Seattle, Washington departments of health and is tailored to meet each region's immunization issues.
State of Alaska
Department of Health and Social Services
Section of Epidemiology
Immunization Program
3601 C Street
Suite 540
Anchorage, AK 99503
(907) 269-8000
FAX: (907) 561-0847
Web site: www.epi.hss.state.ak.us/programs/infect/immune.html

Department of Public Health – Seattle & King County
999 Third Avenue
Suite 900
Seattle, WA 98104
(206) 296-4774
FAX: (206) 296-4803
Web site: www.metrokc.gov/health

B. Institute of Medicine (IOM) Reports and Publications

National Academy Press
2101 Constitution Avenue, NW
P.O. Box 285
Washington, DC 20055
(888) 624-8373
FAX: (202) 334-2451
Web site: www.nap.edu

The Institute of Medicine (IOM) was established in 1970 by the National Academy of Sciences. IOM provides objective, timely, authoritative information and advice about health and science policy to government, the private sector, health professions, and the public. IOM established an Immunization Safety Review Committee in 2001 at the request of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) to review existing and emerging immunization safety concerns during the time period 2001-2003.

The reports and publications listed below related to vaccine safety that have been issued by both IOM and its Immunization Safety Review Committee can all be read on-line for free through the web site of the National Academy Press (NAP). Some reports can also be ordered in print form, depending on how recently they were published.

- Immunization Safety Review: Multiple Immunizations and Immune Dysfunction (2002)
- Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (2001)
- Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism (2001)
- CDC Anthrax Vaccine Safety and Efficacy Research Program: Interim Report (2001)
- The Anthrax Vaccine: Is It Safe? Does It Work? (2002)
- An Assessment of the Safety of the Anthrax Vaccine: A Letter Report (2000)
- Vaccine Safety Forum: Summaries of Two Workshops (1997)
- Risk Communication and Vaccination: Workshop Summary (1997)
- Research Strategies for Assessing Adverse Events Associated with Vaccines: A Workshop Summary (1994)
- Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality (1993)
- Adverse Effects of Pertussis and Rubella Vaccines (1991)

C. Books and Videos

Immunofacts

Facts and Comparisons, Inc.

St. Louis, MO

(800) 223-0554

FAX: (314) 878-5563

Web site: www.drugfacts.com

This looseleaf-style book contains technical information and a glossary of terms that are updated monthly about indications, product availability, dosage, and safety limits for immunological drugs and vaccines.

Vaccines, 3rd edition (1999)

“Safety of Vaccines” chapter, by Robert T. Chen, M.D.

Authors: Stanley A. Plotkin, M.D., and Walter A. Orenstein, M.D., editors

Elsevier Health Science, Inc.

St. Louis, MO

(800) 545-2522

Web site: www.wbsaunders.com

A comprehensive reference book that describes all vaccines currently in use in addition to those about to be licensed, along with many other issues concerning immunization. Of particular interest are chapters covering vaccine safety, vaccine regulation and testing, immunization law, combined vaccines, and immunizing the immunocompromised.

Vaccines: What Every Parent Should Know (revised edition, 1999)

Authors: Paul A. Offit, M.D., and Louis M. Bell, M.D.

Hungry Minds Publishing, Inc.

New York, NY

(800) 434-3422

Web site: www.hungryminds.com

This book contains information about vaccines routinely administered to children and the diseases they prevent, whether vaccines are still necessary; how vaccines work; when to withhold or delay vaccination; vaccine manufacturing, testing, and recommendation processes; multiple and combination vaccinations; and vaccine safety issues.

Vaccinating Your Child: Questions and Answers for the Concerned Parent (2000)

Authors: Sharon G. Humiston, M.D., and Cynthia Good

Peachtree Publishers, Ltd.

Atlanta, GA

(404) 876-8761

Web site: www.peachtree-online.com

This book contains information about vaccines routinely administered to children and the diseases they prevent, whether vaccines are still necessary; how vaccines work; when to withhold or delay vaccination; vaccine manufacturing, testing, and recommendation processes; multiple and combination vaccinations; and vaccine safety issues.

Vaccines: Separating Fact from Fear

Vaccine Education Center at The Children's Hospital of Philadelphia

215-590-9990

Web site: www.vaccine.chop.edu

This 27 minute videotape was created to provide comprehensive, easy to understand answers to parent's questions about the need for and safety of vaccines.

Immunization Techniques: Safe, Effective, Caring

California Department of Health Services' Immunization Branch

(916) 657-2861

This 35 minute video, produced by the California Department of Health Services' Immunization Branch, includes the latest information on injection techniques for immunizing children and adults. The video can be ordered from the Immunization Action Coalition web site at www.immunize.org.